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REMARKS

Claims 1, 6, 14, 16, 18, 21, 24, 27, 34, 38, 44, 45, 48-50, 52, 56-57, 60-61, 66, 74, 76, 78, 81, 84, 87, 94, 98, 104-105, 108-110, 112, 116-117 and 120-124 are pending in the subject application. Applicants have hereinabove cancelled claims 1, 6, 14, 16, 18, 21, 24, 34, 44, 56-57, 61, 66, 74, 76, 78, 81, 84, 87, 94, 98, 104-105, 108-110, 112, 116-117 and 120-124 without prejudice or disclaimer. In addition, applicants have hereinabove added new claims 125-130 and amended claims 27, 38, 45, 48-50, 52 and 60. Support for these amendments may be found inter alia in the specification as follows: claim 27: page 9, lines 12-13; page 40, line 25; page 46, lines 11-16; claim 125-126: page 41, lines 17-23; Figure 10; claims 127-128: page 46, lines 11-25; claim 129: page 46, lines 34-36; claim 130: page 46, line 38 - page 47, line 18. The remaining changes to the claims merely introduce minor grammatical and format changes. These amendments do not involve any issue of new matter. Therefore, entry of this amendment is respectfully requested such that claims 27, 38, 45, 48, 49, 50, 52, 60 and 125-130 will be pending.

The Examiner required restriction to one of the following inventions under 35 U.S.C. §121:

- I. Claims 1, 6, 14, 16, 18, 21, 24, 44, allegedly drawn to isolated nucleic acids encoding an MNR2 protein and a method of making the protein, classified in class 435, subclass 69.1;
- II. Claims 27 and 48, allegedly drawn to a purified MNR2 protein, classified in class 530, subclass 350;

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- III. Claim 34, allegedly drawn to an antibody directed to an MNR2 epitope, classified in class 530, subclass 387.1;
- IV. Claim 38, allegedly drawn to a method of inducing differentiation in somatic motor neurons by expressing MNR2 protein in neural progenitor cells, classified in class 514, subclass 44;
- V. Claims 45, 49, 50, 52, and 60, allegedly drawn to methods of inducing differentiation in somatic motor neurons by administering a purified MNR2 protein, classified in class 514, subclass 2;
- VI. Claims 56 and 57, allegedly drawn to methods of diagnosing chronic neurodegenerative disease by detecting MNR2 nucleic acids, classified in class 435 subclass 6;
- VII. Claims 61, 66, 74, 76, 78, 81, 84, and 104, allegedly drawn to isolated nucleic acids encoding HB9, and a method of making HB9 protein, classified in class 435, subclass 69.1;
- VIII. Claims 87 and 108, allegedly drawn to a purified HB9 protein, classified in class 530, subclass 350;
- IX. Claim 94, allegedly drawn to an anti-HB9 antibody, classified in class 530, subclass 387.1;
- X. Claims 98, 121, 123, allegedly drawn to methods of treatment by delivering MNR2 nucleic acids, classified

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in class 514, subclass 44;

XI. Claims 105, 108-110, 112, 120, 122 and 124, allegedly drawn to methods of treatment by administering a purified HB9 protein, classified in class 514, subclass 2; and

XII. Claims 116 and 117, allegedly drawn to methods of diagnosing chronic neurodegenerative disease by detecting HB9 nucleic acids, classified in class 435 subclass 6.

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The Examiner stated that the inventions are distinct, each from the other because of the following reasons:

The Examiner stated that inventions I-VI are unrelated to invention VII-XII because inventions I-VI pertain to MNR2 nucleic acids, proteins, and antibodies, whereas Inventions VII-XII pertain to HB9 nucleic acids, proteins, and antibodies. The Examiner stated that MNR2 and HB9 are structurally and functionally distinct polypeptides (see e.g. page 6, lines 10-14 of the specification), so their nucleic acids and antibodies are necessarily structurally and functionally distinct.

The Examiner stated that inventions I, II, III are distinct from each other. The Examiner stated that the polynucleotides of Invention I are distinct in chemical structure and function, as well as therapeutic function, from the polypeptides of Invention II and the antibodies of Invention III. Additionally, polynucleotides, polypeptides, and antibodies can be used by materially different methods. The Examiner stated that polynucleotides can be used as detection probes, polypeptides can

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be used for antigen presenting cell priming and antibodies can be used in screening assays, for example. The Examiner stated that the differences between Invention I and Inventions II and III are further underscored by their divergent classification and independent search status.

The Examiner stated that Inventions I and IV are related as product and process of use. The Examiner stated that the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05(h)). The Examiner stated that in the instant case the nucleic acids can be used in a materially different process such as a hybridization assay to detect MNR2.

The Examiner stated that inventions I and V are unrelated. The Examiner stated that inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). The Examiner stated that in the instant case, invention I is a composition that cannot be used in the method of invention V, nor is it produced by the method. So, the Examiner stated that the inventions have different functions, and effects and are not disclosed as capable of use together.

The Examiner stated that inventions I and VI are related as product and process of use. The Examiner stated that the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as

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claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP-S806.05(h)). The Examiner stated that in the instant case the nucleic acids can be used in a materially different process such as production of MNR2 protein.

The Examiner stated that inventions II and III are unrelated to inventions IV and VI. The Examiner stated that the protein and antibody of inventions II and III are not disclosed as being used in the diagnostic and therapeutic nucleic acid-based methods of inventions IV and VI.

The Examiner stated that inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP S806.05(h)). The Examiner stated that in the instant case the protein of invention II can be used in a materially different process such as the production of antibodies.

The Examiner stated that inventions III and V are unrelated. The Examiner stated that the antibody of invention III is not disclosed as being used in the therapeutic method of invention V, nor is it produced or in any way affected by the assay.

The Examiner stated that inventions IV-VI are unrelated to each other. For example, the Examiner stated that inventions IV and V, while both resulting in the same endpoint, arrive there

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through different method steps requiring structurally and functionally different reagents. The Examiner stated that inventions IV and V are not diagnostic methods, as is invention VI, and cannot be used for diagnosis. Likewise the Examiner stated that invention VI cannot be used for therapy.

The Examiner stated that Inventions VII, VIII, and IX are distinct from each other. The Examiner stated that the polynucleotides of Invention VII are distinct in chemical structure and function, as well as therapeutic function, from the polypeptides of invention VIII and the antibodies of Invention IX. Additionally, polynucleotides, polypeptides, and antibodies can be used by materially different methods. The Examiner stated that polynucleotides can be used as detection probes, polypeptides can be used for antigen presenting cell priming and antibodies can be used in screening assays, for example. The Examiner stated that the differences between Invention VII and Inventions VII and IX are further underscored by their divergent colassification and independent search status.

The Examiner stated that Inventions VII and X are related as product and process of use. The Examiner stated that the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05(h)). The Examiner stated that in the instant case the nucleic acids can be used in a materially different process such as a hybridization assay to detect HB9.

The Examiner stated that Inventions VII and XI are unrelated.

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The Examiner stated that inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instant case invention VII is a composition that cannot be used in the method of invention XI, nor is it produced by the method. So, the Examiner stated that the inventions have different functions, and effects and are not disclosed as capable of use together.

The Examiner stated that Inventions VII and XII are related as product and process of use. The Examiner stated that the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The Examiner stated that in the instant case the HB9 nucleic acids can be used in a materially different process such as production of HB9 protein.

The Examiner stated that inventions VIII and IX are unrelated to inventions X and XII. The Examiner stated that the protein and antibody of inventions VIII and IX are not disclosed as being used in the diagnostic and therapeutic nucleic acid-based methods of inventions X and XII.

The Examiner stated that VIII and XI are related as product and process of use. The Examiner stated that the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process

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of using that product (MPEP §806.05(h)). The Examiner stated that in the instant case the protein of invention VIII can be used in a materially different process such as the production of antibodies.

The Examiner stated that inventions IX and XI are unrelated. The Examiner stated that the antibody of invention IX is not disclosed as being used in the therapeutic method of invention XI, nor is it produced or in any way affected by the assay.

The Examiner stated that inventions X-XII are unrelated to each other. For example, inventions X and XI, while both resulting in the same endpoint, arrive there through different method steps requiring structurally and functionally different reagents. The Examiner stated that inventions X and XI are not diagnostic methods, as is invention XII, and cannot be used for diagnosis. The Examiner stated that likewise, invention XII cannot be used for therapy.

The Examiner stated that because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

In response to this restriction requirement, applicants' undersigned attorney, on behalf of applicants, hereby elects, with traverse, to prosecute the invention of Examiner's Group II, i.e. claims 27 and 48, allegedly drawn to a purified MNR2 protein.



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Applicants note that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." [Emphasis added]. Applicants have hereinabove cancelled claims 1, 6, 14, 16, 18, 21, 24, 44, 56, 57, 61, 66, 74, 76, 78, 81, 84, 104, 87, 108, 94, 98, 121, 123, 105, 108-110, 112, 120, 122, 124, 116 and 117 corresponding the Examiner's Groups I and VI-XII, respectively, without prejudice or disclaimer. In addition, applicants note that claim 34 has cancelled and replaced by new claims 125-130. Therefore, applicants regard Group III as pertaining to claims 129-130, i.e. claims drawn to an antibody directed to an MNR2 epitope. Furthermore, applicants have hereinabove added new claims 125-128 which are directed to an MNR2 protein. Applicants request that the restriction of Examiner's Groups II-V from each other be withdrawn in view of the fact that the claims of Examiner's Groups II-V are not independent of each other. Applicants maintain that the claims of Examiner's Groups II-V do not define patentably distinct inventions.

Under M.P.E.P. §802.1, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation, and effect." The Examiner concedes that the inventions of Examiner's Group II and V are related as product and process of use. In addition, the Examiner concedes that the inventions of Examiner's Group II and III are related since the protein of Examiner's Group II can be used in the process of antibody production. Applicants note that the claims of Examiner's Group II, allegedly drawn to a purified MNR2 protein are related to the claims of Examiner's Group III, which are related to the claim of Examiner's Group IV, which is related to the claims of Examiner's Group V, which are related to the

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claims of Examiner's Group II in that the claims in all groups are related to a purified MNR2 protein and processes of use thereof. The claims of Examiner's Group II relate to a purified MNR2 protein, the claims of Examiner's Group III relate to an antibody directed to an MNR2 epitope, the claim of Group IV relates to a method of inducing differentiation in somatic motor neurons by using MNR2 protein in neural progenitor cells, and the claims of Examiner's Group V relate to methods of inducing differentiation in somatic motor neurons by administering a purified MNR2 protein. Therefore, the claims of Examiner's Groups II-V are related.

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Applicants therefore respectfully assert that two or more independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

Additionally, applicants point out that under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

Applicants maintain that there would not be a serious burden on the Examiner if restriction were not required. A search of prior art with regard to Group II, allegedly drawn to a purified MNR2 protein will reveal whether any prior art exists as to an antibody directed to an MNR2 protein epitope, since any such

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antibody will be directed to the MNR2 protein. Also, a search of prior art with regard to Group II, allegedly drawn to a purified MNR2 protein will reveal whether any prior art exists as to a method of inducing differentiation in somatic motor neurons by expressing MNR2 protein in neural progenitor cells or methods of inducing differentiation in somatic motor neurons by administering a purified MNR2 protein, since any such methods will include a method using an MNR2 protein. Since there is no burden on the Examiner to examine Groups II-V in the subject application, the Examiner must examine the entire application on the merits.

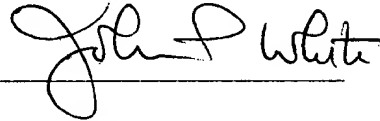
Applicants maintain that claims 27, 38, 45, 48, 49, 50, 52, 60 and 125-130 define a single inventive concept. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement and examine claims 27, 38, 45, 48, 49, 50, 52, 60 and 125-130 on the merits.

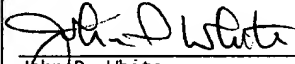
If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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No fee, other than the \$55.00 fee for a one-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
 John P. White Reg. No. 28,678	<u>11/12/03</u> Date

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